Amendments to the Specification:

The following paragraphs are amended:

[0010] FIG. 1 is ~~an elevation~~ a top perspective view of a radial pivot fastener with staples in pre-deployment positions;

[0011] FIG. 2 shows top and bottom perspective views ~~is an elevation view~~ of the radial pivot fastener of FIG. 1 with staples in deployed positions; the top view shows the staples locked-out in the deployed position, while the bottom view shows the staples nested against the bottom of port which is thus "sandwiched" between a housing ring and the staples;

[0064] FIG. 55 shows ~~top~~ bottom and side views of a spring screw fastening system;

[0087] The access port 10 includes a detachable housing 12 which surrounds the outer perimeter of the access port. The detachable housing 12 may be in the form of a molded ring with a frusto-conical outer shape that snaps over an existing access port 10. The housing 12 includes notches or openings 15. The notches house fasteners 14. The notches or openings 15 may take any form necessary to adequately house the fastener 14 while allowing movement of the fastener 14. It is within the scope of the invention that at least three fasteners 14 be present in order to minimize the possibility of movement or dislodgement of the device. As shown in FIGS. 1-4, the fasteners 14 are attached to the ring 12 by a perpendicular segment engaged through a hole and are thereby pivotally connected to the ring 12. The fasteners 14 have a first or pre-deployed position as shown in FIGS. 1 and 3 and a second, deployed or secured position as shown in FIGS. 2 and 4. To move from the first to the second position, the fastener rotates about an axis of the fastener, and in the illustrated embodiment the fastener pivots in a radial plane. The notch 15 accommodates this rotation and a small locking tab 16 holds the fastener in position after rotation. In one embodiment, the fasteners 14 may be 2-legged staples. In another embodiment, the staples are rigid, such that they do not deform during the rotation into the fascia of a patient. For such applications conventional metals are suitable. Furthermore, the staples may be shaped as a "U" or variations thereof, including substantially shaped as:

[0088] When in the second, deployed position, the fastener 14 is held rigidly in place by a locking tab 16, and fastener 14 may flex to allow the fastener to pass into the locked position. The formation of the locking tab 16 may be such that upon movement of the fastener 14 from the first to the second position an audible click is heard by the surgeon to indicate that the fastener 14 is fully engaged by the locking tab 16. The click may also be tactile, allowing the surgeon to feel and confirm through the proximal handle that the fastener is fully engaged by locking tab 16. When in the second position an access port 10 is secured within the housing 12 in the patient by the fasteners 14 which interface with the fascia of the patient. Essentially, the fascia or other bodily tissue is secured between the fasteners 14 and the housing 12 or device 10. As seen in FIG. 2, tips of the fasteners 14 nest against a bottom surface of the access port 10, in effect sandwiching the port between the ring-shaped housing 12 and the fasteners. Furthermore, the housing 12 may contain pegs (not shown) which engage suture holes (not shown) which surround the perimeter of the device 10.

[0089] FIGS. 5-8 depict the access port of FIG. 1 and its interaction with an access port delivery system 20. As shown in FIG. 5, the access port delivery system 20 may have a finger depression 25 on the distal end of a port cover 21 which is used by the operator to help hold the access port and the delivery system in place at the delivery location, stable and properly aligned. The finger depression 25 allows for tactile positioning and finger pressure can be applied to the top of the port cover distal end to increase placement confidence.

[0090] The delivery system 20 comprises a port cover 21 with a distal end having an open bottom that descends down over and captures the access port 10, and a proximal portion that extends upward at an angle therefrom toward a handle. The port cover 21 houses a rod-like plunger 22, a slide pusher 24, and a slide assembly 26, as seen in FIG. 6. The port cover may be formed in any shape necessary to substantially cover the access port 10, and in the illustrated embodiment has a frusto-conical distal end that conforms over the housing 12. The delivery system 20 interacts with a number of different proximal handle configurations, such as shown in FIGS. 9-19.

[0091] The plunger 22 provides the operative means for the delivery system 20 and is connected to a firing means which will be described below. Upon actuation of the firing means the plunger 22 moves in the direction of the access port 10 which, as illustrated in FIG. 6, is downward at an angle to the vertical. This movement causes the slide pusher 24 to be actuated. The slide pusher 24 transfers the energy of the moving plunger 22 to the slide assembly 26. The slide pusher 24 is wedge-shaped as seen best in FIG. 7 so as to cam and deliver downward force to the slide assembly 26 as it slides across the top surface thereof. The slide assembly 26 has a substantially round shape and encircles the access port 10. As seen in FIG. 7, a series of elongated beams 28 spaced around the periphery of the slide assembly 26 extend downward into the notches 15 in the housing 12 and contact the fasteners 14 therein. In other applications, the slide assembly may take a form suitable to the device and housing to be implanted. Upon actuation, the slide assembly 26 is forced in the direction of the access port 10. Alignment tabs 30 as seen from below in FIG. 8 assist the alignment of the slide assembly 26. The alignment tabs 30 are attached to the port cover 21 and interact with the access port 10 to ensure proper alignment. The movement of the slide assembly 26 causes beams 28 attached to the slide assembly 26 to act upon the fasteners 14. The imparting of force on the fasteners 14 allows them to rotate in the ring holes (not shown) and to transcribe an arc defined substantially by the notch 15. This rotation coincides with a movement from the first to the second position discussed above. As the beams 28 continue to be moved towards the access port 10, the fasteners 14 are forced past the locking tabs 16 into tissue below the access port 10 to reach the second position, and are held in place by the locking tabs 16. In this position, with the fasteners 14 deployed as seen in FIG. 8, the access port 10 is rigidly held in place by the fasteners 14 and their interaction with the fascia or other tissue of the patient. At this stage the port cover 21 may be retracted upward from around the access port 10. A feature on the port cover 21 captures the access port 10 therein until deployment is complete, at which time the port is released.

[0092] FIG. 9 shows an access port delivery system complete with a firing means 40 in a pencil-grip style handle attached to the proximal end of the upwardly angled shaft of the delivery system 20, which is shown at 60° from the horizontal. FIG. 10 shows a cross sectional view of the firing means 40 in the starting or loaded position. In this position, the spring 42 is compressed, and a latch 44 that is connected to a rod 46 on the proximal end of the plunger 22 is secured by a rib 48 to prevent the compressed spring 42 from expanding. The firing means has a

button or trigger 50 connected to a lever 52. As shown in FIG. 10 the spring 42 and rod 46 are in a housing 54.

[0093] As shown in the fired position of FIG. 11, upon application of a predetermined force to the trigger 50, the lever 52 acts on the housing 54. The housing 54 pivots on a fulcrum (not shown), this pivoting action lifts the latch 44 above the end of the rib 48, thus dislodging the rod 46 and allowing it to advance distally. Upon lifting, the spring force of the compressed spring 42 drives the plunger 22 in the direction of the access port and actuates the mechanism therearound as discussed above. In such a configuration the plunger travel, speed and impact force can be determined to meet the application needs. As tested, the plunger travel was between 0.25 and 0.75 in, and can develop up to 50 lb. of force on the plunger, depending upon the spring used in the application. Deployment of the plunger 22 is thus instantaneous with a high impact speed, though a slower deployment mechanism controlled by the surgeon may be provided.

[0094] An alternative handle configuration to the spring driven mechanism described above is shown in FIG. 12. FIG. 12 shows a palm grip actuated firing mechanism 60. The palm grip is a very simple lever design requiring only a single moving part to move the plunger 22. In a first or starting position as shown in FIG. 13, there is a moving handle 61 (or lever), a stationary handle 62 (or housing), a pivot point 64, and an actuating tip 66. The handle is oriented generally horizontally and attaches to the upwardly-angled shaft of the delivery system 20, which is shown at 60° from the horizontal.

[0095] In operation the user squeezes on the moving handle 61 forcing it in the direction of the stationary handle 62 to the fired position of FIG. 14. This movement forces the actuating tip 66 which is connectively engaged with the moving handle 61 and the pivot point 64 in a direction opposite the direction of movement of the movable handle 61. Through the use of the simple lever action, a comparatively small force applied to the moving handle 61 (lever) is amplified through the pivot point 64 and applied by the actuating tip 66 to the rod-like plunger 22. The plunger 22 is moved downward at an angle by the actuating tip 66 in the direction of the access port 10 and actuates the mechanism therearound as discussed above. The force produced by the palm grip actuated device is limited only by the strength of the user, as tested the device was capable of producing in excess of 50 lb. of force with a plunger travel of 0.25 in. Deployment speed is controlled by the operator. Alternatively, a geared mechanism could be produced that could produce equal or greater force although require a greater travel distance for

the moving handle 61. The force produced by the device shown in FIGS. 12-14 could also be altered as necessary by moving the pivot point 64 nearer the plunger 22 to produce more force, or away from the pivot point to produce less force.

[0096] Yet another alternative firing means/handle configuration is shown in FIGS. 15-19. The pistol grip firing means 70 includes a trigger 72 having geared teeth 73 located on one end, a gear 74 which meshes with the geared teeth 73, a rack 75 driven by the gear 74, and a spring 76. The rack may also include a means 78 for gripping the plunger 22, which is slip fit within the delivery system 20 shaft.

[0097] The operative progression is shown in FIGS. 17-19. In the starting position of FIG. 17, the trigger is extended and the spring is under little or no tension. The geared teeth 73 are meshed with corresponding teeth of the gear 74 and with teeth on the rack 75. The plunger 22 is in the extended position. When the trigger 72 is depressed, the geared teeth 73 actuate the gear 74 and in turn cause the rack 75 to compress the spring 76 into the full spring recoil position, as shown in FIG. 18. At a predetermined distance the geared teeth 73 no longer engage the gear 74. At this point the gear 74 is free to spin. The stored energy in the spring 76 forces the rack 75 to move toward the plunger 22. The free spinning gear 74 allows the rack 75 to move, which in turn forces the rod-like plunger towards the access port 10 and actuates the mechanism therearound as discussed above, and as seen in the fired position of FIG. 19.

[0100] In FIG. 20 a further embodiment of the present invention is shown. The use of NiTi (Nitinol) or SMA alloy materials is well known in the medical arts as discussed above. As shown in FIG. 20 NiTi fasteners are shown in a pre-deployment state. The fasteners 14 are arranged in a continuous wireform with legs ~~and~~ attached to the access port 10 through holes therein. In operation the fasteners 14 are depressed into the fascia of the patient to secure the access port. The NiTi fasteners 14 have the unique ability to change their shape when heated, e.g. to body temperature. As shown in a post-deployment state in FIG. 21, when the fasteners are deployed they can change shape to bend under and towards the center of the access port 10 and secure it in place.

[0101] In FIG. 22 the fasteners 14 are shown with straight legs 80 parallel to a base of the access port 10 in a deployed state. Alternative configurations include curved legs 81 as shown in FIG. 23. By virtue of the continuous wireform, the fasteners/legs are formed by narrow closed-

loop projections with blunt tips. Using the curved legs 81 which track into the base of the access port 10, the fascia can be pinched between the fastener and the underside of the access port. A further alternative is shown in FIG. 24 where the tips of the continuous wireform fastener legs 81 are coated with a molded tip 82. The molded tip may be formed in a shape that will assist in piercing the fascia of the patient. This eliminates the need to form the fastener 14 into a shape for piercing. Additionally, the tips 82 may be formed of a bio-absorbable material.

[0102] In another embodiment of the present invention, the NiTi fastener can be continuously formed ~~in a~~ as one-piece along with an insert-molded ring 84, as in FIGS. 25-27. The use of the ring 84 allows for the NiTi fasteners 14 to be formed with a continuous one-piece construction. After the insert-molded ring 84 with the fasteners 14 is formed, the ends of the legs 80 can be ground off to produce individual substantially U-shaped fasteners 14. The ring 84 insures that the fasteners 14 can be inserted as a unit as discussed above, and the grinding of the legs ensures a sufficiently sharp point to more easily pierce the fascia. As shown in FIGS. 25 and 27, the legs can be formed and positioned in the ring 84 so that after bending due to heating, the legs 80 face internally to the access port 10 or externally to the access port 10.

[0103] Yet another embodiment of the present invention is a two-part radial slide fastening system as shown in FIGS. 28-34. FIG. 28 shows a guide 90 formed with a plurality of individual fasteners 14. The guide 90 may be a molded circular flange-like member as shown. The fasteners 14 are slidable in the guide 90 from a first to a radially inward second position. In operation the guide 90 is placed over the access port 10 and aligned with notches 15. The fasteners 14 are formed of a spring like material and shaped to attach to the access port 10. The fasteners 14 are slid from a first position as shown in FIG. 28 to a second position as shown in FIG. 29. Small protrusions on each fastener 14 may snap into place in suture holes of the access port 10, as seen in FIG. 29. The fasteners 14 pierce the fascia and securely hold the access port 14 thereto. As previously described, the fasteners may have straight or curved legs, the former shown in FIGS. 28 and 29 and the latter in FIG. 30. After the sliding of all of the fasteners from the guide 90 onto the access port 10, the guide may be removed if it is not part of the final implanted device. Alternatively, the guide 90 may also be a permanent part of the implantable device.

[0105] FIG. 33 and FIG. 34 depict pre- and post-installation stages, respectively, for yet another two-part fastening device comprising an applicator 112 and a ring 110 having NiTi fasteners 114. In practice, the ring 110 is inserted into the applicator 112. The applicator 112 is placed over the access port 10 with the fasteners 114 aligned with notches 115 and holes 106. The fasteners 114 are forced through the holes 106 and engage the fascia of the patient upon which the access port 10 rests. Through the heating process, the fasteners 114 change shape and secure the access port to the fascia. After a predetermined time, the applicator can be removed.

[0107] Yet another embodiment of the present invention is shown in FIG. 39. In FIG. 39 the fasteners 14 are slidably installed in the access port 10. This may be accomplished by cold molding of the NiTi fastening system into the device, and allows positive attachment and repeatable re-positioning. Through the use of an installation tool 120, the fasteners are forced through holes in the bottom of the access port 10 and engage the fascia. By installing the fasteners as an integral part of the access port 10, no ring or housing is needed as discussed above for housing the fasteners. The installation tool 120 could be part of a triggering device as disclosed herein. FIG. 39 is a pre-installation stage and FIG. 40 shows the fastener 14 in the engaged position.

[0111] FIG. 41 depicts a helical coil fastener 201, which may optionally be utilized with a port that features a tubing connector extending from the center of the base. The corkscrew-type design is mounted to a separate disc 203 which snaps to the port at tabs 202, or alternatively, may be mounted to the port itself, centered on the base plate. The disc or port is manually affixed to the tissue by rotation of the disc or port, which causes the coil to travel on a helical path through the tissue. In one embodiment, the coil can have a sharpened tip.

[0112] A variation of the helical coil fastener is depicted in FIG. 42. FIG. 42 depicts a flat spiral spring 204 that is deflected downward to begin its path through the tissue. The deflecting implement ~~is~~ 205 may be withdrawn following implantation, allowing the spring to compress during healing. Compression of the spring will reduce the profile of the implanted coil fastener and can reduce the likelihood of pain induction. Tabs 202 are used for locking a port or other device into the fastener.

[0113] FIGS. 43-47 <u>and 55</u> depict a horizontal coil implantation system. In the horizontal coil system, a metal coil is used horizontally to stitch the port to the tissue. It is well known that such coils can pierce and hold in tissues from their use as mesh tacks in minimally invasive hernia procedures. In this case, the coil travels parallel to the tissue surface instead of perpendicularly, as in the helical coil fasteners described above (see FIG. 55). <u>One example of such a coil is formed of 0.014 inch D wire having a pitch of 0.0100 inch.</u> A small <u>deployment</u> tool <u>206 with a slotted driver</u> is envisioned to aid in driving the coil <u>208</u> through the tissue and the mating holes <u>207</u> in the base <u>coil receptacle 209</u> (see FIG<u>S</u>. 46 <u>and 47</u>). Such holes could be straight holes through a ridge on the bottom of the base (see FIGS. 44, 45 and 47), or curved holes molded into a flat-surfaced base. <u>The coil holes shown in FIG. 47 are shown spaced apart 0.100 inch, the same as the coil pitch, and having a diameter of 0.240 inch.</u> A top view of a base is shown in FIG. 43. It is envisioned that the last hole would be blind, and that the end of the coil would be shaped in a crossbar that could slide over an incline and lock into place, such as into a slot. <u>Desirably, a solid stop for advancement of the coil is provided, and there may be a latch configuration wherein the driver end of the coil catches on the underside of the base.</u> A variation would feature a path for the coil that curves around the port or base edge, facilitating tool access to the coil. This can also be accomplished by varying the flexibility of the coil. A tube can be added to the tool as a shroud in order to keep the rotating coil from picking up strings of tissue before it travels through the holes.

[0114] FIGS. 48 to 62 depict various embodiments of a metal suture system. This method of port fixation involves the creation of one or multiple closed metal loops below the port base, by using the base itself as a means to close a loop formed by curved metal members <u>211</u> (see, e.g. FIGS. 48 and 52). This may be done both with one-piece and two-piece systems, whereby a two-piece system may have a ring <u>210</u> that attaches to the port or other device ~~with the system of~~ <u>by snap-fitting with tabs 202 as shown in</u> FIG. 50. One embodiment includes a deflection tool to separate the point of the metal member from contact with the base allowing the member tip to begin its path downward through the tissue. This can be a circular disc or the port itself. After the point has traveled some distance, the tool is withdrawn, permitting the curved member to then follow a path intersecting with the base. Likewise, another embodiment includes multiple members curved in two planes, such that rotation of the base affects the creating of multiple loops.

[0115] An alternate method to achieve such a loop is with a curved pin 212 (hook or needle) that is inserted through the base after it is in its intended tissue location, as seen in FIGS. ~~51,~~ 53 and 54. Such a pin by nature follows an arc through the tissue and can easily be directed back to the port base. Such a pin can be made to lock in place after full travel by adding a right angle bend 213 to the pin that snaps into a slot 214 on the base, or other such well-known means (see FIG. 57). A variation on this theme includes an additional straight section on the end of the pin, parallel to the curved section ~~(FIG. 51)~~. A lever arm 215 is used to drive the curved section through the base and to the completion of its intended travel ~~(see FIGS. 49 and 58-62)~~.

[0116] In yet another embodiment, a two-piece system may be used wherein the port attaches to a folding baseplate 218 with sharp, curved extensions 217 (see FIG. 56). The folded plate is placed on the tissue with the extensions pointed toward the tissue. When the baseplate is unfolded (flattened) the extensions are driven 90 degrees in a rotary path (see FIG. 56). The port is then snapped to the baseplate, locking the extensions in position. In one embodiment, the points of the extensions would overlap or cross over those from the other half, semi-shielding the points.